Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Osteonics® Spinal System Rod/Plate System (RPS)

Proprietary Name:	Techtonix™ System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II Spinal Interlaminal Fixation Orthosis, 21 CFR 888.3050 Pedicle Screw Spinal System, 21 CFR 888.3070
Device Product Code:	87 MNH: Spondylolisthesis Spinal Fixation System 87 KWP: Appliance, Fixation, Spinal Interlaminal
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	January 26, 2005

Predicate Device Identification

The features of the Techtonix™ System are substantially equivalent to the features of the Osteonics® Spinal System Rod/ Plate System (RPS) which was determined substantially equivalent via 510(k) K991055.

Description of Device Modification

This submission is intended to expand the Osteonics® Spinal System Rod/ Plate System product line by adding the Techtonix™ System, a low profile posterior plate system. Similar to its predicate device, the Techtonix™ System is comprised of anatomical shaped plates and bone screws available in a variety of lengths, and blockers (which tighten the bone screws to the plates). The components of the subject device are fabricated from Titanium alloy as described in ASTM F-136 and ISO 5832-3. The Techtonix™ System will be provided non-sterile.

Intended Use:

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System Rod/Plate System and Techtonix™ System are indicated for:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogneic origin with degeneration of the disc confirmed by history and radiographic studies)
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics® Spinal System Rod/Plate System and Techtonix™ System are indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

- In addition, the Osteonics® Spinal System Rod/Plate System and Techtonix™ System are indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

Statement of Technological Comparison:

The subject components share the same intended use and basic design concepts as that of the predicate device. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Ms. Simona Voic
Regulatory Affairs Project Manager
Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Re: K050189
Trade/Device Name: Osteonics® Spinal System Rod/Plate System and Techtonix™ System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, KWP
Dated: January 26, 2005
Received: January 27, 2005

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

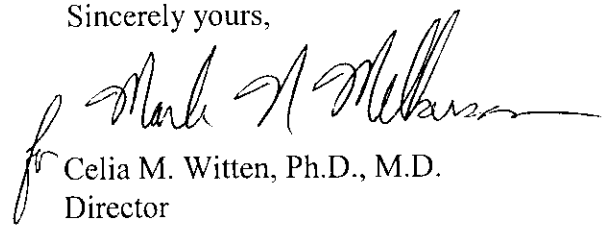
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050189

Indications for Use

510(k) Number (if known): K_____

Device Name: Osteonics® Spinal System Rod/Plate System and Techtonix™ System

Indications For Use:

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System Rod/Plate System and Techtonix™ System are indicated for:

- Long and short curve scoliosis
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050189

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